

APR 28 2004

Special 510(k)
Concerto™ Bipolar Needle Electrode

March 26, 2004

Summary of Safety and Effectiveness

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This 510(k) summary is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR §807.92.

K040785

General Information

Submitter: Boston Scientific Corporation
One Boston Scientific Place
Natick, MA 01760
508-652-5003

Contact Person: Nicholas Condakes

General Provisions

Trade Name: Concerto™ Bipolar Needle Electrode

Classification Name: Electrode, Electrosurgical

Name of Predicate Devices

Reflect Bipolar/Monopolar Needle Electrode

Classification

Class II

Performance Standards

The Concerto Bipolar Electrode has been designed to comply with the applicable sections of ANSI/AAMI American Standard for Electrosurgical Devices HF-18/2001 and the International Electrotechnical Commission Standard for Electrosurgical Devices, IEC 60601-2-2/2001.

**Intended Use
and Device
Description**

Concerto™ Bipolar Needle Electrode is intended to be used in conjunction with a Boston Scientific radiofrequency (RF) generator for the thermal coagulation necrosis of soft tissues, including partial or complete ablation of nonresectable liver lesions. The Concerto™ Bipolar Needle Electrode is a disposable, electrosurgical device used for coagulation necrosis of soft tissue. The device consists of a needle with two electrically independent opposing arrays that are contained within an insulated delivery cannula. The arrays are attached to a handle mechanism that allows the arrays to be individually deployed out from the cannula into the targeted tissue. The Concerto™ Bipolar Needle Electrode is connected to Boston Scientific radiofrequency (RF) generator so that energy passes between the two arrays and heats the tissue surrounding and in between the arrays. No grounding pads are required due to the device's Bipolar technology.

**Summary of
Substantial
Equivalence**

The Concerto™ Bipolar Needle Electrode has been tested and compared to the predicate device. All data gathered demonstrate this device as substantially equivalent. No new issues of safety or efficacy have been raised.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 28 2004

Mr. Nicholas Condakes
Regulatory Specialist II
Boston Scientific Corporation
One Boston Scientific Place
Natick, Massachusetts 01760

Re: K040785

Trade/Device Name: Concerto™ Bipolar Needle Electrode
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: II
Product Code: GEI
Dated: March 26, 2004
Received: March 29, 2004

Dear Mr. Condakes:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,

Miriam C. Provost
for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications For Use

510(k)
Number
(if known)

K040785

Device Name: Concerto™ Bipolar Needle Electrode

Indications
for Use

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(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ☒
(Per 21 CFR 801 Subpart D)

Miriam C. Provost
(Division Sign-Off)

Over-The-Counter Use ☐
(21 CFR 807 Subpart C)

**Division of General, Restorative,
and Neurological Devices**